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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/692,874	10/24/2003	Scott C. Mayer	AHP-98396 D1	1962
25291	7590	02/18/2005	EXAMINER	
WYETH PATENT LAW GROUP 5 GIRALDA FARMS MADISON, NJ 07940			MAIER, LEIGH C	
			ART UNIT	PAPER NUMBER
			1623	

DATE MAILED: 02/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/692,874	Applicant(s) MAYER, SCOTT C.	
	Examiner Leigh C. Maier	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-8 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 5-8 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>10/24/03</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Priority

This instant application is filed as a divisional of USSN 09/444,736. The parent application has now issued as a patent. The first paragraph of the specification must be amended to update the priority information.

Claim Rejections - 35 USC § 112 – 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5 and 6 recite methods of treating or inhibiting proliferative disorders. Typically “inhibition” is used regarding processes, such as the underlying mechanism causing a disorder, and “prevention” or “prophylactic treatment” is used regarding the disorder or disease, *per se*. In these claims, it would appear that “inhibiting” is used to mean “preventing.”

Claims 5 and 6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for prevention of hyperproliferative vascular disorders (such as restenosis), does not reasonably provide enablement for prevention of such disorders in the general population. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Art Unit: 1623

Many of the factors regarding undue experimentation have been summarized in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Circ. 1988) as follows:

- (1) The quantity of experimentation necessary (time and expense);
- (2) The amount of direction or guidance presented;
- (3) The presence or absence of working examples of the invention;
- (4) The nature of the invention;
- (5) The state of the prior art;
- (6) The relative skill of those in the art;
- (7) The predictability or unpredictability of the art; and
- (8) The breadth of the claims.

The claims are drawn to methods including the prevention of hyperproliferative vascular disorders in a mammal "in need thereof." The specification discusses a population (surgical patients) that would be in need of prevention, but Applicant does not appear to contemplate that the claims be limited to this population. Otherwise, claim 7 would not be limiting. However, the specification does not describe how patients in need would be identified. While prophylactic treatment of surgical patients (with other therapeutic agents) is well known in the art, general prophylactic treatment is not well known. The specification does not present any working example that would provide guidance for prophylactic treatment of any subjects in need other than surgical patients. Therefore, one of ordinary skill would require undue experimentation, expending time and monetary resources to use this invention commensurate with the scope recited in the claims.

Claim Rejections - 35 USC § 112 – 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter that the applicant regards as his invention.

Art Unit: 1623

Claims 5-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims recite a definition of variables R¹ through R⁸ that includes both “acyl of 2-7 carbon atoms” and “benzoyl.” It would appear that the former would also include the latter. However, because “benzoyl” is listed separately, it is not clear what “acyl of 2-7 carbon atoms” is meant to include and exclude. The claims are rendered vague and indefinite.

Allowable Subject Matter

The claims appear to be free of the prior art. AU et al (EP 551675) teaches the use of lactobionamides as inhibitors of bacterial adhesion. The reference does not teach the instant lactobionamides; nor does it teach antiproliferative activity.

Regarding the methods for “inhibiting” (or preventing) particular disorders, Applicant might consider deleting “or inhibiting” from claims 5 and 6 and add claims drawn to prevention of hyperproliferative vascular disorders (or restenosis) wherein the method is limited to patients who have undergone vascular or transplantation surgery. These claims would be considered to be enabled and free of the art.

Art Unit: 1623

Examiner's hours, phone & fax numbers

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (571) 272-0656. The examiner can normally be reached on Tuesday, Thursday, and Friday 7:00 to 3:30 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson (571) 272-0661, may be contacted. The fax number for Group 1600, Art Unit 1623 is (703) 872-9306.

Visit the U.S. PTO's site on the World Wide Web at <http://www.uspto.gov>. This site contains lots of valuable information including the latest PTO fees, downloadable forms, basic search capabilities and much more.

Leigh C. Maier

Leigh C. Maier
Patent Examiner
February 16, 2005